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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,496	01/16/2004	Stefan Franzen	297/178/2	7690
25297      7590      02/26/2008 JENKINS, WILSON, TAYLOR & HUNT, P. A. 3100 TOWER BLVD., Suite 1200 DURHAM, NC 27707				
EXAMINER				
SESSON, BRADLEY L				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
02/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/759,496

**Applicant(s)**

FRANZEN ET AL.

**Examiner**

Bradley L. Sisson

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 28 December 2007 has been entered.

### ***Claim Objections***

2. Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As a result of the amendment to claim 1, the limitations of claim 37 seem to be found in said claim 1, and as such, claim 37 does not further limit claim 1 from which it depends.

### ***Claim Rejections - 35 U.S.C. § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 44, and 45 are indefinite with respect to what constitutes the metes and bounds of “approximately spherical.”
6. Claim 1 is confusing as a result of the redundant use of the clause: “the target nucleic acid sequence additionally comprises at least one nanoparticle attached to the target nucleic acid sequence.”
7. Claim 1 is indefinite with respect to what constitutes the metes and bounds of “specifically hybridizes” and “stringent hybridization conditions.”
8. Claim 1 is indefinite with respect to what constitutes the metes and bounds of a “metal-atom entity.”
9. Claim 1 is confusing where at line 8 is stated: “and exhibits one of surface plasmon resonance and an interband transition.” It appears that applicant is attempting to identify a *Markush* Group. Applicant is urged to consider amending claim 1 such that it recites >>selected from the group consisting of<<. (See MPEP 2173.05(h)).
10. Claim 1 is indefinite with respect to what constitutes the metes and bounds of “interband transition.”
11. Claims 2-43, which depend from claim 1, fail to overcome these issues and are similarly rejected.
12. Claims 1-45 are indefinite with respect to what constitutes the “sequence” in a “target nucleic acid sequence” as well as a “target sequence. While a cDNA, mRNA, DNA and RNA

molecule may comprise a sequence of nucleotides, the polymer is but a single molecule.

Applicant is urged to adopt language that clarifies that the target is a DNA, mRNA, polynucleotide, nucleic acid, etc., and not a "sequence."

13. Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: performing a comparison temperature measurement step. As presently worded, one is to perform but a single temperature measurement, however, this one data point in and of its self is not dispositive of whether the target nucleic acid is present. Rather, one must compare the measured temperature to a solid support that has no nanoparticles immobilized thereto. The claimed method, however, does not require one to take this baseline measurement. Accordingly, it is not possible to ever reach the conclusion that the target is or is not present.

14. Claim 26 is confusing as to the metes and bounds ascribed to the term "derived."

15. Claim 27 is indefinite with respect to what constitutes "a sequence from a gene."

16. Claim 28 is confusing where it states that "the capture probe comprises or is suspected to comprise a mutation to be detected." Seemingly, the nucleotide sequence of the capture probe is (or should be) known, not unknown, as the claim suggests. Applicant is urged to consider adopting language that reflects that the capture probe is directed against a target nucleic acid that "comprises or is suspected to comprise a mutation" of interest, as is indicated in claim 29.

17. Claim 38 is confusing as a result of the expression "one of." It appears that applicant is attempting to identify a *Markush* Group. Applicant is urged to consider amending claim 38 such that it recites >>selected from the group consisting of<<. (See MPEP 2173.05(h)).

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18. Claim 45 is confusing where in line 3 there appears: "an at least least 10 fM concentration."

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 1-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

21. As presently worded, the claimed method is to result in the detection of a nucleic acid such as an mRNA, or corresponding cDNA, known as an expressed sequence tag or EST, for which no known utility exists. To that end, it is noted that claim 3 requires the target to comprise RNA; claim 4 requires the target to comprise cDNA, and claim 26 requires the target to be either mRNA or cDNA. While the claimed method could result in the detection of the required hybridization complex, such does not indicate or otherwise limit that the information obtained meets the substantial utility requirement.

22. A question of overall operability of the claimed method exists. As presently worded, the claimed method has been construed as encompassing the detection of a target nucleic acid in a sample. The sample may or may not actually comprise the target nucleic acid. As presently worded, the method requires that "hybridization complex" be used. By the mandatory presence of a hybridization complex, the signal will always be positive, irrespective of the sample actually comprising the target sequence. With regard to this issue, applicant is urged to consider

rewording the claims so that one can detect a target nucleic acid in a sample wherein the sample is suspected of comprising a target nucleic acid. And that the target nucleic acid is capable of forming the recited hybridization complex.

23. Claims 1-45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Conclusion***

24. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner, Art Unit 1634